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Our Case No. 8627-1901
Client Ref. No. PA-5145-CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Henrik S. Klint et al.

Serial No.: 10/813,783

Filing Date: March 30, 2004

For: EMBOLIZATION METHOD FOR ENDOVASCULAR OCCLUSION

Examiner: Julian W. Woo

Group Art Unit No.: 3773

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop: Appeal Brief - Patents
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P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the final Office Action dated November 20, 2008, Applicants submit this Appeal Brief in support of the appeal of the final rejection of claims 1-22. It is respectfully submitted that the final rejection of claims 1-22 should be reversed for the following reasons.

I. Real Party in Interest

The real party in interest in the present appeal is Cook Incorporated, the assignee of the entire right, title and interest in the application.

II. Related Appeals and Interferences

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned or Cook Inc. "which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal."

III. Status of Claims

Claims 1-22 are currently pending and have been rejected.

The rejections of claims 1-22 are being appealed in this appeal.

IV. Status of Amendments

All claim amendments have been entered and considered by the Examiner.

V. Summary of Claimed Subject Matter

The claims are directed to a method of endovascular occlusion of a blood vessel area. Specifically, independent claim 1 is directed to a method for endovascular occlusion of a blood vessel area, independent claim 19 is directed to a method for endovascular occlusion of an aneurysm, and independent claim 20 is directed to a method for endovascular occlusion of a blood vessel lumen. Each of claims 1, 19, and 20 require: 1) abutting a first wall portion of a blood vessel area/aneurysm/lumen with a front end of a wire, thereby column loading the wire body and frictionally locking the front end against the first wall portion; 2) continuing to mechanically push the wire body out of a distal opening of a catheter, thereby curving a section of the wire body, which is substantially straight in a predetermined unloaded shape, toward a second wall portion of the blood vessel area/aneurysm/lumen, wherein the section of the wire body frictionally locks against the second wall portion of the blood vessel area/aneurysm/lumen when the section is column loaded between the first and second wall portions due to the wire body being mechanically pushed forward, thereby forming a portion of the wire body crossing the blood vessel area/aneurysm/lumen that is

frictionally locked to the first wall portion and the second wall portion due to the column loading; 3) physically separating the wire body from the catheter by pushing en entirety of the wire body out of the distal opening of the catheter; 4) occluding blood flow in the blood vessel area/aneurysm/lumen to be occluded using the section of the wire body frictionally locked between the first and second wall portions, wherein the blood flow is occluded after the wire body is physically separated from the catheter and after the catheter is removed from the blood vessel area/aneurysm/lumen to be occluded; and 5) forming a thrombus at a location of the wire body after the wire body is physically separated from the catheter and after the catheter is removed from the blood vessel area/aneurysm/lumen to be occluded. The elements of independent claims 1, 19, and 20 are recited below with citations to the preferred embodiments described in the specification.

1. A method for endovascular occlusion of a blood vessel area, comprising:

advancing a catheter (18) percutaneously and transluminally until a distal opening of said catheter (19) is located at a blood vessel area to be occluded (17, 21);

providing a wire body (1) comprising a front end (2, 2", 2"'), a back end (5, 5', 5"), and a section connecting said front end and said back end (4), wherein said section (4) is substantially straight in a predetermined unloaded shape, a length of said section (4) being larger than a diameter of said blood vessel area (17, 21);

inserting said wire body (1) into said catheter (18), said section of said wire body (4) being substantially straight in said predetermined unloaded shape within said catheter (18);

mechanically pushing said wire body (1) forward through said catheter (18) until said front end of said wire body (2, 2", 2"') is pushed out of said distal opening of said catheter (19);

abutting a first wall portion of said blood vessel area (17, 21) with said front end of said wire body (2, 2", 2"'), thereby column loading said wire body (1) and frictionally locking said front end (2, 2", 2"') against said first wall portion;

continuing to mechanically push said wire body (1) out of said distal opening of said catheter (19), thereby curving said section of said wire body (4) toward a second wall portion of said blood vessel area (17, 21), wherein said section of said wire body (4) frictionally locks against said second wall portion of said blood vessel area (17, 21) when said section (4) is column loaded between said first and second wall portions due to said wire body (1) being mechanically pushed forward, thereby forming a portion of said wire body crossing said blood vessel area (4, 20) that is frictionally locked to said first wall portion and said second wall portion due to said column loading;

physically separating said wire body (1) from said catheter (18) by pushing an entirety of said wire body (1) out of said distal opening of said catheter (19);

occluding blood flow in said blood vessel area to be occluded (17, 21) using said section of said wire body frictionally locked between said first and second wall portions (4, 20), wherein said blood flow is occluded after said wire body (1) is physically separated from said catheter (18) and after said catheter (18) is removed from said blood vessel area to be occluded (17, 21); and

forming a thrombus at a location of said wire body (1) after said wire body (1) is physically separated from said catheter (18) and after said catheter (18) is removed from said blood vessel area to be occluded (17, 21).

19. A method for endovascular occlusion of an aneurysm, comprising:

advancing a catheter (18) percutaneously and transluminally until a distal opening of said catheter is located at an aneurysm to be occluded (17);

providing a wire body (1) comprising a front end (2''), a back end (5''), and a section connecting said front end and said back end (4), said front end (2'') and said back end (5'') being curved and said section (4) being substantially straight in a predetermined unloaded shape, a length of said section being larger than a diameter of said aneurysm (17), wherein said wire body (1) is made of a thread (12) extending helically around a center line of said wire body (1) and said wire body (1) is

characterized by the absence of occlusion hairs, an inner lumen of said catheter (18) being sized substantially to said wire body (1);

inserting said wire body (1) into said catheter (18), said section of said wire body (4) being substantially in said predetermined unloaded shape within said catheter (18);

mechanically pushing said wire body (1) forward through said catheter (18) until said front end of said wire body (2") is pushed out of said distal opening of said catheter (19);

abutting a first wall portion of said aneurysm (17) with said front end of said wire body (2"), thereby column loading said wire body (1) and frictionally locking said front end (2") against said first wall portion;

continuing to mechanically push said wire body (1) out of said distal opening of said catheter (19), thereby curving said section of said wire body (4) toward a second wall portion of said aneurysm (17), wherein said section (4) frictionally locks against said second wall portion when said section (4) is column loaded between said first and second wall portions due to said wire body being mechanically pushed forward, thereby forming a portion of said wire body (20) crossing said aneurysm (17) and frictionally locked to said first wall portion and said second wall portion due to said column loading;

repeating said continuing step until said section of said wire body (1) has assumed a complexly curved shape, whereby said section (4) repeatedly crosses said aneurysm (17) and frictionally locks against wall portions of said aneurysm (17) when said section (4) is column loaded between said wall portions due to said wire body (1) being mechanically pushed forward, said section (4) thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints;

physically separating said wire body (1) from said catheter (18) by pushing an entirety of said wire body (1) out of said distal opening of said catheter (19);

occluding blood flow in said aneurysm (17) with said wire body (1) having a complexly curved shape that is frictionally locked between said wall portions,

wherein said blood flow is occluded after said wire body (1) is physically separated from said catheter (18) and after said catheter (18) is removed from said aneurysm (17); and

forming a thrombus at a location of said wire body (1) after said wire body (1) is physically separated from said catheter (18) and after said catheter (18) is removed from said aneurysm (17).

20. A method for endovascular occlusion of a blood vessel lumen, comprising:

advancing a catheter (18) percutaneously and transluminally until a distal opening of said catheter (19) is located at a blood vessel lumen to be occluded (21);

providing a wire body (1) comprising a front end (2), a back end (5, 5'), and a section connecting said front end and said back end (4), said front end (2) in a predetermined unloaded shape being formed as a spiral with a decreasing helix diameter (3) in the direction of said front end (2), a largest helix diameter (3) corresponding to a diameter of said blood vessel lumen (21), and said section being substantially straight in said predetermined unloaded shape (4), a length of said section (4) being at least six times said diameter of said blood vessel lumen (21), wherein said wire body (1) is made of a thread (12) extending helically around a center line of said wire body (1) and said wire body (1) is characterized by the absence of occlusion hairs, an inner lumen of said catheter (18) being sized substantially to said wire body (1);

inserting said wire body (1) into a proximal end of said catheter (18), said catheter (18) thereby loading said wire body (1) into a substantially straight condition;

mechanically pushing said wire body (1) forward through said catheter (18) until said front end of said wire body (2) is pushed out of said distal opening of said catheter (19);

abutting a first wall portion of said blood vessel lumen (21) with said front end of said wire body (2), thereby frictionally locking said front end (2) against said first wall portion;

retracting said catheter (18) to create a free length of said section of said wire body extending between said front end of said wire body and said distal opening of said catheter (4);

continuing to mechanically push said wire body (1) out of said distal opening of said catheter (19) thereby column loading said section (4) as said wire body (1) is mechanically pushed and curving said section of said wire body (4) toward a second wall portion of said blood vessel lumen (21), wherein said section (4) frictionally locks against said second wall portion due to said column loading of said section (4), thereby forming a portion of said wire body (1) crossing said blood vessel lumen (21) and frictionally locked to said first wall portion and said second wall portion;

repeating said continuing step until said section (4) of said wire body (1) has assumed a complexly curved shape, whereby said section (4) repeatedly crosses said blood vessel lumen (21) and frictionally locks against wall portions of said blood vessel lumen (21) due to said column loading of said section (4), said section (4) thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints;

physically separating said wire body (1) from said catheter (18) by pushing an entirety of said wire body (1) out of said distal opening (19) of said catheter (18);

occluding blood flow in said blood vessel lumen to be occluded (21) using said wire body (1) having a complexly curved shape that is frictionally locked between said wall portions, wherein said blood flow is occluded after said wire body (1) is physically separated from said catheter (18) and after said catheter (18) is removed from said blood vessel lumen to be occluded (21); and

forming a thrombus at a location of said wire body (1) after said wire body (1) is physically separated from said catheter (18) and after said catheter (18) is removed from said blood vessel lumen to be occluded (21).

VI. Ground of Rejection to be Reviewed on Appeal

A. The Examiner has rejected claim 1 as being anticipated under 35 U.S.C. § 102(b) by Guglielmi, et al. (U.S. Pat. No. 5,122,136).

B. The Examiner has rejected claim 19 as being unpatentable under 35 U.S.C. § 103(a) over Guglielmi in view of Kupiecki, et al. (U.S. Pat. No. 5,669,931).

C. The Examiner has also rejected claim 20 as being unpatentable under 35 U.S.C. § 103(a) over Guglielmi in view of Kupiecki, et al. (U.S. Pat. No. 5,669,931).

VII. Argument

A. Independent claim 1 is not anticipated by Guglielmi et al.

Applicants seek review of the Examiner's rejection of claim 1 as being anticipated under 35 U.S.C. § 102(b) by Guglielmi, et al. (U.S. Pat. No. 5,122,136). The arguments below are directed to independent claim 1. For purposes of the present appeal, dependent claims 2-18 and 21-22 stand or fall with claim 1.

The ultimate issue before the Board is whether Guglielmi anticipates independent claim 1 by disclosing each and every element set forth in the claims. MPEP § 2131. Applicants respectfully submit that Guglielmi fails to disclose all the limitations of independent claim 1, and therefore, Guglielmi cannot and does not anticipate the claims under 35 U.S.C. § 102(b).

As recited in claim 1, the method for endovascular occlusion of a blood vessel area requires abutting a first wall portion of a blood vessel area with a front end of a wire, thereby column loading the wire body and frictionally locking the front end against the first wall portion. The wire body is required to comprise a front a section connecting a front end and a back end, the section being substantially straight in a predetermined unloaded shape. Claim 1 further requires the wire body continue to be mechanically pushed out of a distal opening of a catheter, thereby curving a section

of the wire body toward a second wall portion of the blood vessel area. The section of the wire body is required to frictionally lock against the second wall portion of the blood vessel area when the section is column loaded between the first and second wall portions due to the wire body continuing to be mechanically pushed forward. Thus, a portion of the wire body crossing the blood vessel area and that is frictionally locked to the first wall portion and the second wall portion is required to form due to the column loading.

The method of claim 1 also requires physically separating the wire body from the catheter by pushing the entirety of the wire body out of the distal opening of the catheter, and occluding blood flow in the blood vessel area/aneurysm/lumen to be occluded using the section of the wire body frictionally locked between the first and second wall portions. The blood flow is required to be occluded after the wire body is physically separated from the catheter and after the catheter is removed from the blood vessel area/aneurysm/lumen to be occluded. A thrombus is required to be formed at a location of the wire body after the wire body is physically separated from the catheter and after the catheter is removed from the blood vessel area/aneurysm/lumen to be occluded.

Referring to claim 1, Guglielmi fails to disclose each of these elements. In the Office Action dated November 20, 2008, the Examiner generally asserts that Guglielmi discloses each and every element of claim 1 in at least Figures 1-5; Col. 4, lines 18-12; Col. 6, lines 48-Col. 8, lines 42-47.

With regard to the elements of:

> 1) providing a wire body comprising a front end, a back end, and a section connecting said front end and said back end, wherein said section is substantially straight in a predetermined unloaded shape, a length of said section being larger than a diameter of said blood vessel area;
>
> 2) abutting a first wall portion of said blood vessel area with said front end of said wire body, thereby column loading said wire body and frictionally locking said front end against said first wall portion; and
>
> 3) continuing to mechanically push said wire body out of said distal opening of said catheter, thereby curving said section of said wire body toward a second wall portion of said blood vessel area, wherein said section of said wire body frictionally locks against said second wall portion of said blood vessel area when said section is column loaded

> between said first and second wall portions due to said wire body being mechanically pushed forward, thereby forming a portion of said wire body crossing said blood vessel area that is frictionally locked to said first wall portion and said second wall portion due to said column loading,

the Examiner has provided no substantive analysis and simply presents a conclusory statement that Guglielmi "discloses inherent column-loading and frictionally locking of the wire body as it [is] mechanically pushed into a blood vessel area and thrombus formation after physical separation of the wire body from the catheter . . . . That is the wire body inherently buckles and bends as it contacts the walls of a blood vessel area, fills the area, and is held in the area." Office Action dated November 20, 2008, p. 7. In support of this argument, the Examiner appears to be relying on Figures 4 and 5, which illustrate the insertion of the third embodiment (depicted in Figure 3) into an aneurysm. Office Action dated November 20, 2008, p. 2, 7. However, contrary to the Examiner's assertions, Guglielmi fails to teach these elements.

Guglielmi discloses three different embodiments for performing endovascular electrothrombosis. Col. 2, lines 19-27; Col. 4, lines 1-14, 36-62. As shown in Figs. 1 and 1A, the first embodiment includes a secondary coil 28 that is prebiased to form a cylindrical or conical spiral or a helix. The prebiased spiral 28 is connected to a stainless steel coil 26. Col. 6, lines 18-47. In operation, the spirally shaped secondary coil 28 is placed into an aneurysm 64 and a current is applied to a guidewire 10 from an external voltage source. The current causes the spirally shaped coil 28 to become positively charged. Col. 6, lines 48-55. The positively charged coil (electrode) attracts negatively charged white blood cells, red blood cells, platelets, and fibrinogen, thereby causing a thrombic mass to form about the spirally shaped coil 28. *Id.*; Col. 2, ll. 19-27. Once the thrombic mass is formed, the secondary coil is detached from the stainless steel coil 26 by continuing to apply current while a portion 18 of the stainless steel coil 26 is exposed to blood, thereby causing a portion of the stainless steel coil 26 to disintegrate. Col. 6, ll. 55-62. Upon detaching the secondary coil 28, the guidewire is withdrawn, leaving the secondary coil 28 embedded within the thrombus formed within the aneurysm. Col. 6, ll. 62-65.

As shown in Figs. 2, 2A, the second embodiment includes a short wire body that is straight, but as described in the specification, this wire body does not include a bonding location (e.g., 22, 52 of Figures 1 and 3) for separating the wire body from the guidewire. (Col. 6, line 66 to col. 7, line 11). Thus, this embodiment does not disclose a wire body that is released into the aneurysm.

The third embodiment is shown in Figs. 3-5. The third embodiment includes a free and open platinum coil 56 made of a platinum alloy that is "particularly pliable" and that is "distinguished by its length of 1 to 50 cm and by its flexibility." As shown in Figs. 4-5, the flexible platinum coil 56 is fed into an aneurysm. Due to its pliable and flexible nature, the coil assumes an irregular free-form configuration. Once the coil is located within the aneurysm, a positive electric current is applied to the platinum coil 56 to form a thrombic mass about the platinum coil 56. Col. 8, ll. 5-15.

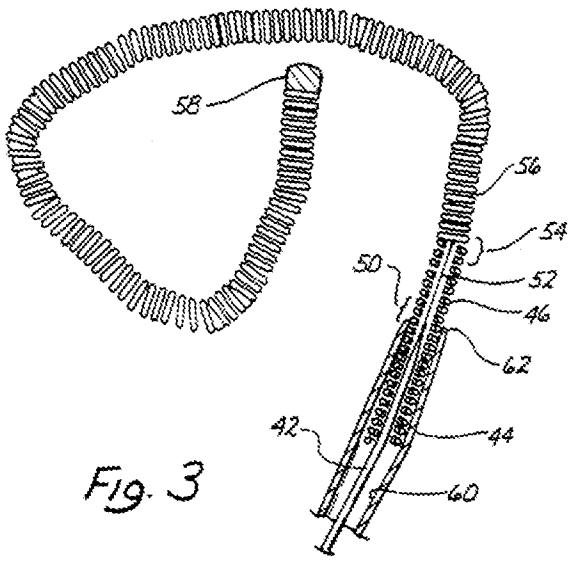

Fig. 3

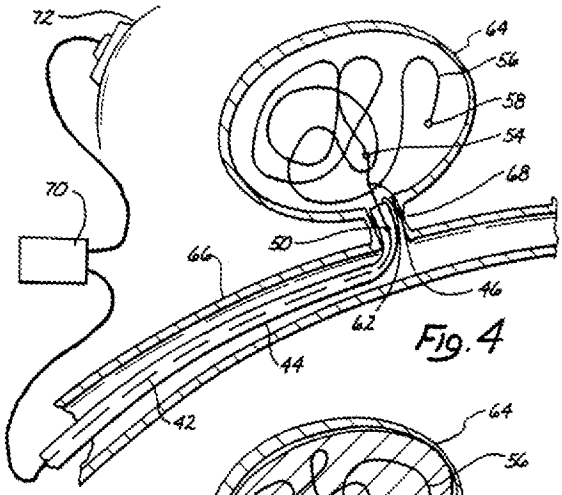

Fig. 4

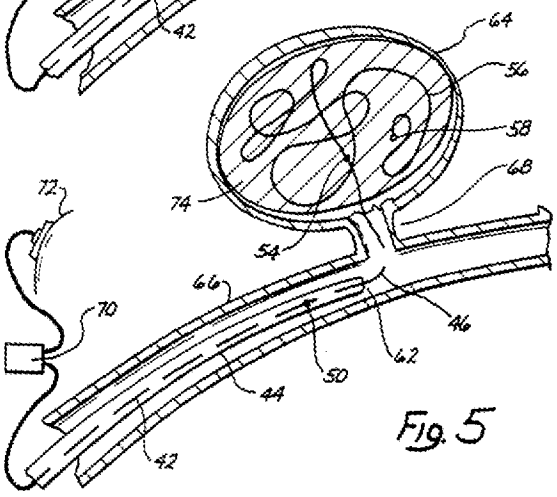

Fig. 5

However, contrary to the Examiner's assertions, Figures 3, 4, and 5 clearly show the flexible platinum coil 56 in a bent, free-form configuration within the

aneurysm 64 in which no portion of the flexible platinum coil 56 is in contact with, much less frictionally locked against any portion of a wall of the aneurysm 64. Indeed, this free-form configuration of the flexible platinum coil 56 in the aneurysm 64 is entirely consistent with the specification, which explicitly states that the platinum coil 56 is "particularly pliable" and "contains no internal reinforcement and is a free and open coil." Col. 7, lines 48-60. Indeed, because the platinum coil 56 is very pliable and has no internal reinforcement, the coil 56 has no structural integrity and is therefore not capable of being prebiased. *See Id.* Accordingly, when the platinum coil 56 is deployed it assumes a complexly curved shape that does not contact the walls of the aneurysm 64, as shown in Figures 3-5. Moreover, contrary to the Examiner's assertions, there is no evidence in either the Figures or the specification of Guglielmi to even suggest that the curved shape of the platinum coil 56 shown in Figures 3-5 is due to the coil 56 contacting a wall of the aneurysm 64. Furthermore, because platinum coil 56 has no internal reinforcement and is very pliable, it is not capable of frictionally locking between a first and second wall portion of the blood vessel area to be occluded by column loading, as recited in amended claim 1.

Indeed, changing the flexible pliable platinum coil to a wire having sufficient structural rigidity to frictionally lock against a vessel wall under column loads, as recited in amended claim 1, would change the principle operation of Guglielmi. *See* MPEP § 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."). The principle operation of the flexible platinum coil (or secondary coil) of Guglielmi is to simply provide an electrode that can be inserted into an aneurysm and occlude blood flow through electrothrombosis. Thus, it would not be obvious to modify the flexible, pliable electrode of Guglielmi to frictionally lock to sides of the blood vessel area wall and occlude blood flow using the wire itself, as required by claim 1.

Furthermore, contrary to the Examiner's assertions, Guglielmi fails to inherently disclose forming a portion of the wire body crossing the blood vessel area

that is frictionally locked to a first wall portion and a second wall portion due to column loading, as required by claim 1. Nowhere does Guglielmi disclose or even suggest contacting the aneurysm wall with the coil. Accordingly, Guglielmi also fails to disclose frictional locking of a coil between first and second wall portions due to column loading, as required by claim 1. Indeed, Figures 4 and 5 explicitly show the coil not contacting any portion of the aneurysm wall. Thus, it appears the Examiner is asserting that because the flexible platinum wire may be capable of contacting two portions of an aneurysm wall, elements 2) and 3) of claim 1 are inherently disclosed. However, as discussed above, Guglielmi fails to suggest contacting an aneurysm wall, much less frictional locking a coil to a first wall portion and a second wall portion due to column loading. Further, "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). Moreover, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. MPEP § 2112(IV); In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Accordingly, Figures 4 and 5 actually show that forming a portion of the wire body crossing the blood vessel area, which is frictionally locked to a first wall portion and a second wall portion due to column loading, as required by claim 1, is not inherent.

Guglielmi also fails to disclose element 1), which requires providing a wire body comprising a front end, a back end, and a section connecting said front end and said back end, wherein said section is substantially straight in a predetermined unloaded shape, a length of said section being larger than a diameter of said blood vessel area. In other words, claim 1 requires the section to span the entire distance from the front end to the back end of the wire body. The section is also required to be substantially straight when no external force is applied to it. That is, the section

is substantially straight both when housed within the catheter and when advanced out of the distal end of the catheter, provided that no external force is applied to the section. Indeed, it is only when the section is column loaded that it frictionally locks and bends between the first and second portions of the blood vessel area, as required by claim 1. In contrast, when the flexible platinum coil 56 of Guglielmi is unrestrained/unloaded (i.e. the external force has been removed), it assumes the freeform, nonlinear shape shown in Figures 3-5. This is because the coil 56 has no internal reinforcement or structural integrity. *See* Col. 7, lines 48-60; Figs. 3-5. Further, the only straight portion of the coil 56 shown in Figure 3 is the end itself. Accordingly, because it is the end itself that is straight, it is impossible for the straight end portion to connect the front and back ends of the wire body as required by claim 1. Thus, Guglielmi fails to disclose a straight section connecting the front and back ends of a wire body, wherein the section is substantially straight in a predetermined unloaded shape, as required by claim 1.

With regard to elements:

> 4) physically separating said wire body from said catheter by pushing an entirety of said wire body out of said distal opening of said catheter,
>
> 5) occluding blood flow in said blood vessel area to be occluded using said section of said wire body frictionally locked between said first and second wall portions, wherein said blood flow is occluded after said wire body is physically separated from said catheter and after said catheter is removed from said blood vessel area to be occluded; and
>
> 6) forming a thrombus at a location of said wire body after said wire body is physically separated from said catheter and after said catheter is removed from said blood vessel area to be occluded,

the Examiner also fails to provide any substantive analysis and presents mere conclusory statements. Regarding element 4) of claim 1, the Examiner asserts that Guglielmi's disclosure of "electrolytically disintegrating coil 46" discloses "physically separating the wire body from the catheter by pushing an entirety of the wire body out of the distal opening of the catheter," as required by claim 1. Office Action dated November 20, 2008, p. 3. As set forth above, Guglielmi discloses separating a single coil into multiple pieces by electrolytically dissolving a portion thereof. In

contrast, the wire body of claim 1 is required to be physically separated from a catheter, not from itself. Further, claim 1 requires the wire body to be separated from the catheter by pushing the wire body out of the distal opening of the catheter. This method is not disclosed in Guglielmi because the coil is separated by applying a current to dissolve an exposed portion of the coil, not by pushing the entirety of the coil out of a catheter.

The Examiner also argues that Guglielmi inherently discloses "occlusion of blood flow in the blood vessel area and thrombus formation after physical separation of the wire body from the catheter." Office Action dated November 20, 2008, p. 7. As support for this position, the Examiner relies upon Col. 8, lines 42-47, which state, "It has further been discovered that thrombus 74 continues to form even after detachment from guidewire 42. It is believed that a positive charge is retained on or near the coil 56 which therefore continues to attract platelets, white blood cells, red blood cells and fibrinogen within aneurysm 64." However, this passage of Guglielmi simply reinforces the fact that a thrombus must be formed using electrothrombosis prior to dissolving the coil from the guidewire; it is only by virtue of the remaining positive charge that the already created thrombosis continues to grow. Further, as set forth above, inherency may not be established by mere probabilities or possibilities. MPEP § 2112(IV).

Additionally, Guglielmi actually teaches away from occluding the blood flow "using the section of the wire body frictionally locked between the first and second wall portions of the blood vessel area," as required by claim 1. As discussed above, Guglielmi discloses occluding blood flow by forming a thrombus around the coil via electrothrombosis. Once the current has been applied to the coil and the thrombus is formed, it is the thrombus that occludes the blood flow, not the coil itself. Thus, the coil disclosed in Guglielmi and the wire body required by claim 1 serve entirely different purposes. The coil disclosed in Guglielmi is merely an electrode that serves to form a thrombus via electrothrombosis; that is, the coil is not an occluding device itself. In contrast, the wire body required by claim 1 is the actual occluding device.

Furthermore, Guglielmi fails to disclose, and actually teaches away from occluding blood flow and forming a thrombus after the wire body is separated from the catheter and the catheter is removed from the area of the blood vessel to be

occluded, as required by claim 1. As described above, Guglielmi occludes blood flow through electrothrombosis. In order for electrothrombosis to occur, current must be able to flow from the external voltage source to the electrode (secondary coil 28, stainless steel portion 36, platinum coil 56). If the electrode is detached from the stainless steel coil, current can no longer flow to the electrode and the electrode cannot be positively charged. If the electrode cannot be positively charged, the thrombus cannot be formed. Thus, it would be impossible for the coil disclosed by Guglielmi to occlude blood flow after the wire body is separated from the catheter and the catheter is removed from the area of the blood vessel to be occluded. Furthermore, it would not be obvious to modify the electrode of Guglielmi to form a thrombus after it is detached from the stainless steel coil since this would change the principle operation of the reference. As discussed above, the principle operation of the electrode (platinum coil, secondary coil), and indeed the entire device taught by Guglielmi, is to occlude an aneurysm by creating a thrombus using electrothrombosis. *See* MPEP § 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."). Accordingly, Guglielmi fails to disclose all the elements of, and indeed teaches away from the method of claim 1.

B. Independent claim 19 is not obvious over the combination of Guglielmi et al. (U.S. Pat. No. 5,122,136) and Kupiecki, et al. (U.S. Pat. No. 5,669,931)

Applicants seek review of the Examiner's rejection of claim 19 as being unpatentable under 35 U.S.C. § 103(a) by Guglielmi, et al. (U.S. Pat. No. 5,122,136) in view of Kupiecki, et al. (U.S. Pat. No. 5,669,931). The arguments below are directed to independent claim 19.

The ultimate issue before the Board is whether the combination of Guglielmi, et al. and Kupiecki, et al. disclose all the limitations of claim 19. Applicants

respectfully submit that the Examiner has not set forth a proper prima facie case of obviousness, and therefore, the Examiner's rejection should be reversed.

Claim 19 is directed to a method for endovascular occlusion of an aneurysm. Like claim 1, claim 19 requires the same elements of claim 1 discussed above of:

> 1) providing a wire body comprising a front end, a back end, and a section connecting said front end and said back end, said front end and said back end being curved and said section being substantially straight in a predetermined unloaded shape, a length of said section being larger than a diameter of said aneurysm . . .;
>
> 2) abutting a first wall portion of said aneurysm with said front end of said wire body, thereby column loading said wire body and frictionally locking said front end against said first wall portion;
>
> 3) continuing to mechanically push said wire body out of said distal opening of said catheter, thereby curving said section of said wire body toward a second wall portion of said aneurysm, wherein said section frictionally locks against said second wall portion when said section is column loaded between said first and second wall portions due to said wire body being mechanically pushed forward, thereby forming a portion of said wire body crossing said aneurysm and frictionally locked to said first wall portion and said second wall portion due to said column loading;
>
> 4) physically separating said wire body from said catheter by pushing an entirety of said wire body out of said distal opening of said catheter;
>
> 5) occluding blood flow in said aneurysm with said wire body having a complexly curved shape that is frictionally locked between said wall portions, wherein said blood flow is occluded after said wire body is physically separated from said catheter and after said catheter is removed from said aneurysm; and
>
> 6) forming a thrombus at a location of said wire body after said wire body is physically separated from said catheter and after said catheter is removed from said aneurysm.

As set forth above in connection with claim 1, Guglielmi fails to disclose these same elements required by claim 19. Furthermore Guglielmi also fails to teach or suggest:

> repeating said continuing step until said section of said wire body has assumed a complexly curved shape, whereby said section repeatedly crosses said aneurysm and frictionally locks against wall portions of said aneurysm when said section is column loaded between said wall portions due to said wire body being mechanically pushed

forward, said section thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints

As set forth above, Guglielmi fails to disclose forming a portion of the wire body crossing the blood vessel area that is frictionally locked to a first wall portion and a second wall portion due to column loading. For these same reasons, Guglielmi also fails to disclose using a wire body section that repeatedly crosses and frictionally locks against wall portions of the aneurysm when the section is column loaded between the wall portions.

Further, the other reference cited by the Examiner, Kupiecki et al., is merely relied upon as disclosing a wire body having curved ends. The Examiner has not even alleged that Kupiecki, et al. teaches or suggests the above described elements of claim 19. Consequently, the combination of Guglielmi and Kupiecki fail to teach or suggest all of the limitations of claim 19, and for at least these reasons, the combination of Guglielmi and Kupiecki does not render claim 19 unpatentable.

C. Independent claim 20 is not obvious over the combination of Guglielmi et al. (U.S. Pat. No. 5,122,136) and Kupiecki, et al. (U.S. Pat. No. 5,669,931)

Applicants seek review of the Examiner's rejection of claim 20 as being unpatentable under 35 U.S.C. § 103(a) by Guglielmi, et al. (U.S. Pat. No. 5,122,136) in view of Kupiecki, et al. (U.S. Pat. No. 5,669,931). The arguments below are directed to independent claim 20.

Claim 20 is directed to a method for endovascular occlusion of a blood vessel lumen. As set forth above in connection with claims 1 and 19, the combination of Guglielmi, et al. and Kupiecki, et al. fail to teach or suggest all the limitations of claim 20. Consequently, claim 20 is also allowable for at least the reasons provided above in sections VII(A) and VII(B).

VIII. Conclusion

Applicants respectfully submit that claims 1-22 are allowable over the prior art of record. As argued above, Applicants submit that Guglielmi, et al. fails to disclose each and every element set forth in claims 1-18, 21, and 22. Further, the combination of Guglielmi, et al. and Kupiecki, et al. fails to teach or suggest all the elements of claims 19 and 20. As explained above, the Examiner has impermissibly and incorrectly asserted that several elements of independent claims 1, 19, and 20 are inherently disclosed by Guglielmi, et al., despite contrary evidence in the specification and drawings thereof. Accordingly, Applicants request that the Examiner's rejection of claims 1-22 be reversed and Applicants' application be allowed as presented.

Respectfully submitted,

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Claims Appendix

1. (Previously Presented) A method for endovascular occlusion of a blood vessel area, comprising:

advancing a catheter percutaneously and transluminally until a distal opening of said catheter is located at a blood vessel area to be occluded;

providing a wire body comprising a front end, a back end, and a section connecting said front end and said back end, wherein said section is substantially straight in a predetermined unloaded shape, a length of said section being larger than a diameter of said blood vessel area;

inserting said wire body into said catheter, said section of said wire body being substantially in said predetermined unloaded shape within said catheter;

mechanically pushing said wire body forward through said catheter until said front end of said wire body is pushed out of said distal opening of said catheter;

abutting a first wall portion of said blood vessel area with said front end of said wire body, thereby column loading said wire body and frictionally locking said front end against said first wall portion;

continuing to mechanically push said wire body out of said distal opening of said catheter, thereby curving said section of said wire body toward a second wall portion of said blood vessel area, wherein said section of said wire body frictionally locks against said second wall portion of said blood vessel area when said section is column loaded between said first and second wall portions due to said wire body being mechanically pushed forward, thereby forming a portion of said wire body crossing said blood vessel area that is frictionally locked to said first wall portion and said second wall portion due to said column loading;

physically separating said wire body from said catheter by pushing an entirety of said wire body out of said distal opening of said catheter;

occluding blood flow in said blood vessel area to be occluded using said section of said wire body frictionally locked between said first and second wall portions, wherein said blood flow is occluded after said wire body is physically

separated from said catheter and after said catheter is removed from said blood vessel area to be occluded; and

forming a thrombus at a location of said wire body after said wire body is physically separated from said catheter and after said catheter is removed from said blood vessel area to be occluded.

2. (Original) The method according to claim 1, wherein said blood vessel area to be occluded is an aneurysm.

3. (Previously Presented) The method according to claim 2, wherein said front end of said wire body is curved in said predetermined unloaded shape at least 120° and said back end of said wire body is curved in said predetermined unloaded shape.

4. (Previously Presented) The method according to claim 1, further comprising repeating said continuing step until said section of said wire body has assumed a complexly curved shape, whereby said section repeatedly crosses said blood vessel area and frictionally locks against wall portions of said blood vessel area when said section is column loaded between due to said wire body being mechanically pushed forward, said section thereby forming curvatures in said complexly curved shape, the curvatures varying continuously without breakpoints.

5. (Original) The method according to claim 1, wherein said blood vessel area to be occluded is a vessel lumen.

6. (Previously Presented) The method according to claim 5, further comprising retracting said catheter between said abutting and said continuing steps, wherein a free length of said section of said wire body extends between said front end of said wire body and said distal opening of said catheter, said continuing step thereby column loading said section as said wire body is mechanically pushed.

7. (Original) The method according to claim 6, further comprising repeating said continuing step until said section of said wire body has assumed a complexly curved shape, whereby said section repeatedly crosses said blood vessel area and frictionally locks against wall portions of said blood vessel area, said section thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints.

8. (Previously Presented) The method according to claim 7, wherein said front end of said wire body in said predetermined unloaded shape is formed as a spiral with a decreasing helix diameter in the direction of said front end, a largest helix diameter corresponding generally to said diameter of said blood vessel area, and said length of said section of said wire body being at least six times said diameter of said blood vessel area.

9. (Original) The method according to claim 1, further comprising repeating said continuing step until said section of said wire body has assumed a complexly curved shape, whereby said section repeatedly crosses said blood vessel area and frictionally locks against wall portions of said blood vessel area, said section thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints.

10. (Previously Presented) The method according to claim 1, wherein said front end of said wire body is curved in said predetermined unloaded shape at least 120°.

11. (Previously Presented) The method according to claim 1, wherein said back end of said wire body is curved in said predetermined unloaded shape between 140° and 340°.

12. (Original) The method according to claim 1, wherein said length of said section of said wire body is at least 20 mm.

13. (Original) The method according to claim 1, wherein said length of said section of said wire body is at least 90 mm.

14. (Original) The method according to claim 1, wherein said wire body is made of a thread extending helically around a center line of said wire body.

15. (Original) The method according to claim 1, wherein said wire body is further characterized by the absence of occlusion hairs, an inner lumen of said catheter being sized substantially to said wire body.

16. (Original) The method according to claim 15, wherein said wire body is made of a thread extending helically around a center line of said wire body.

17. (Original) The method according to claim 1, wherein said section of said wire body has a spring constant of $c = P/e$ measured on a 50 mm long portion of said wire body, P being an axially acting applied force measured in N and e being a change of length measured in mm, said spring constant being in the interval of $0.0015 \text{ N/mm} \leq c \leq 0.08 \text{ N/mm}$.

18. (Original) The method according to claim 1, wherein said front end of said wire body has a largest external diameter ranging from 2 to 13 mm, said length of said section of said wire body ranges from 30 and 300 mm, and said back end of said wire body has a largest external diameter ranging from 4 to 8 mm.

19. (Previously Presented) A method for endovascular occlusion of an aneurysm, comprising:

advancing a catheter percutaneously and transluminally until a distal opening of said catheter is located at an aneurysm to be occluded;

providing a wire body comprising a front end, a back end, and a section connecting said front end and said back end, said front end and said back end being curved and said section being substantially straight in a predetermined unloaded shape, a length of said section being larger than a diameter of said aneurysm, wherein said wire body is made of a thread extending helically around a center line of said wire body and said wire body is characterized by the absence of occlusion hairs, an inner lumen of said catheter being sized substantially to said wire body;

inserting said wire body into said catheter, said section of said wire body being substantially in said predetermined unloaded shape within said catheter;

mechanically pushing said wire body forward through said catheter until said front end of said wire body is pushed out of said distal opening of said catheter;

abutting a first wall portion of said aneurysm with said front end of said wire body, thereby column loading said wire body and frictionally locking said front end against said first wall portion;

continuing to mechanically push said wire body out of said distal opening of said catheter, thereby curving said section of said wire body toward a second wall portion of said aneurysm, wherein said section frictionally locks against said second wall portion when said section is column loaded between said first and second wall portions due to said wire body being mechanically pushed forward, thereby forming a portion of said wire body crossing said aneurysm and frictionally locked to said first wall portion and said second wall portion due to said column loading;

repeating said continuing step until said section of said wire body has assumed a complexly curved shape, whereby said section repeatedly crosses said aneurysm and frictionally locks against wall portions of said aneurysm when said section is column loaded between said wall portions due to said wire body being

mechanically pushed forward, said section thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints;

physically separating said wire body from said catheter by pushing an entirety of said wire body out of said distal opening of said catheter;

occluding blood flow in said aneurysm with said wire body having a complexly curved shape that is frictionally locked between said wall portions, wherein said blood flow is occluded after said wire body is physically separated from said catheter and after said catheter is removed from said aneurysm; and

forming a thrombus at a location of said wire body after said wire body is physically separated from said catheter and after said catheter is removed from said aneurysm.

20. (Previously Presented) A method for endovascular occlusion of a blood vessel lumen, comprising:

advancing a catheter percutaneously and transluminally until a distal opening of said catheter is located at a blood vessel lumen to be occluded;

providing a wire body comprising a front end, a back end, and a section connecting said front end and said back end, said front end in a predetermined unloaded shape being formed as a spiral with a decreasing helix diameter in the direction of said front end, a largest helix diameter corresponding to a diameter of said blood vessel lumen, and said section being substantially straight in said predetermined unloaded shape, a length of said section being at least six times said diameter of said blood vessel lumen, wherein said wire body is made of a thread extending helically around a center line of said wire body and said wire body is characterized by the absence of occlusion hairs, an inner lumen of said catheter being sized substantially to said wire body;

inserting said wire body into a proximal end of said catheter, said catheter thereby loading said wire body into a substantially straight condition;

mechanically pushing said wire body forward through said catheter until said front end of said wire body is pushed out of said distal opening of said catheter;

abutting a first wall portion of said blood vessel lumen with said front end of said wire body, thereby frictionally locking said front end against said first wall portion;

retracting said catheter to create a free length of said section of said wire body extending between said front end of said wire body and said distal opening of said catheter;

continuing to mechanically push said wire body out of said distal opening of said catheter thereby column loading said section as said wire body is mechanically pushed and curving said section of said wire body toward a second wall portion of said blood vessel lumen, wherein said section frictionally locks against said second wall portion due to said column loading of said section, thereby forming a portion of said wire body crossing said blood vessel lumen and frictionally locked to said first wall portion and said second wall portion;

repeating said continuing step until said section of said wire body has assumed a complexly curved shape, whereby said section repeatedly crosses said blood vessel lumen and frictionally locks against wall portions of said blood vessel lumen due to said column loading of said section, said section thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints;

physically separating said wire body from said catheter by pushing an entirety of said wire body out of said distal opening of said catheter;

occluding blood flow in said blood vessel lumen to be occluded using said wire body having a complexly curved shape that is frictionally locked between said wall portions, wherein said blood flow is occluded after said wire body is physically separated from said catheter and after said catheter is removed from said blood vessel lumen to be occluded; and

forming a thrombus at a location of said wire body after said wire body is physically separated from said catheter and after said catheter is removed from said blood vessel lumen to be occluded.

21. (Previously Presented) The method according to claim 1, wherein said steps of mechanically pushing said wire body comprises pushing on a guidewire coupled to said back end of said wire body.

22. (Previously Presented) The method according to claim 1, wherein said steps of mechanically pushing said wire body comprises pushing on a stylet abutting said back end of said wire body, said stylet being unconnected to said wire body.

Evidence Appendix

None.

Related Proceedings Appendix

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned or Cook Inc. "which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal." As such, there are no "decisions rendered by a court or the Board in any proceeding" to submit.